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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,431

01/03/2007

Gerhard Tivig

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS

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BRIARCLIFF MANOR, NY 10510

EXAMINER

BITAR, NANCY

ART UNIT

PAPER NUMBER

2624

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/595,431	<b>Applicant(s)</b> TIVIG ET AL.	
	<b>Examiner</b> NANCY BITAR	<b>Art Unit</b> 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 7/2/2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3,4,12,14,16-18,20-22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,4,12,14,16-18,20-22 and 24-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to the reference that the reference WO 93/187706 can not be relied on since only English abstract was provided by the examiner and the technical description set forth in the abstract is too brief to ascertain what Balakirev discloses a .Examiner requested a translation to the Russian reference and will provide the translation once available. Upon further search, Examiner used a new ground of rejection Zaleski et al ( US 2003/0101076).

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 3, 4, 12, 14, 16-18, 20-22, 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seely et al (US 2003/0117296) in view of Zaleski et al (2003/0101076).

As to claim 20, Seely et al teaches the method of automatically displaying medical measurement data in which a computer: receives the medical measurement data (107, figure 1) automatically converts in real time the received measurement data into data for a histogram including a updated in real time, (paragraph [0075], [0085]), during the conversion, generates a cumulative curve indication of the medical measurement data the cumulative curve being cumulative of the series of histogram values (figure 5, and 6) and displays the histogram with the cumulative curve superimposed, the histogram and the cumulative curve having common axes and a common scales (paragraph [0088-0089]). While Seely et a meets a number of the limitations of the claimed invention, as pointed out more fully above, Seely teaches the variability display (paragraph [0085-0090] but fails to specifically teach the histogram includes an updates in real time values and generating a cumulative curve indicative of the medical measurement data the cumulative curve being cumulative of the series of histogram values. Specifically, Zaleski et al. teaches in FIG. 1, the system is implemented in computer hardware and software configured to operate on a dedicated software application and Web-enabled hardware computing system to access raw medical facts about patients extracted from lifetime clinical records and telemetry from available modalities (such as ventilators, pulse oximeters, ECG monitors, core temperature probes, etc.); and to convert this raw data into mathematical models for clinical outcome and real-time patient state prediction. Zelski clearly teaches in figure 9 the model (expected) trajectories are compared with the measured (actual) trajectories of the patient. The comparison is evaluated to determine the degree of "likeness" or "sameness" between the expected and actual trajectories. Finally, by combining all trajectories together, it is possible to determine a cumulative estimate of "sameness" using a .chi..sup.2-square test to show

Art Unit: 2624

that the patient's cardiovascular parameters are either following or not following an expected path ( see paragraph [0058-0060]) . It would have been obvious to one of ordinary skill in the art to generate in real-time the histogram data and the cumulative curve in Seely display in order to have an efficient system which is capable of acting as the foundation on which to establish predictive methodologies for clinical application that would provide significant advantages in the process of defining a truly valuable decision support system for the clinician thus providing a convenient way to perform complex comparative trend analysis .Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

As to claim 3, Seely et al teaches a method as claimed in claim 5, further including: filling the histogram is filled with measurement data from a time window advancing in real time with selectable fixed length (see figure 6, note that for each patient parameter  $v_{sub.k}$ , a user, typically an attending physician, may select the number of data points  $m_{sub.k}$  to collect in order to perform the variability analysis).

As to claim 4, Seely et al teaches a method as claimed in claim 20, wherein, during the conversion, the computer generates aids for the retrospective analysis of the histograms in the form of selectable functions that can be displayed on a viewing screen and outputs them together with the converted data combined as picture signals (note that the process 110 may be selected by a user from among a plurality of variability analysis options using a user interface 117, see paragraph [0061]).

The limitation of claim 12 has been addressed in claim 20 above..

Seely teaches the limitation of claim 14 wherein the retrospective analysis aids include a deviation readout (The simplest method for computing variability parameters involves the calculation of mean and standard deviation of the frequency distribution of a selected data set. This information can be updated continuously and displayed visually as a graph. Statistical interpretation of the frequency distribution is dependent upon whether the distribution is normal or lognormal. There are standardized means of evaluating whether a distribution is accurately represented by a normal or log-normal curve, which include evaluation of kurtosis and skew. By calculating the kurtosis and skew, the user may be directed towards choosing an appropriate distribution. By evaluating the frequency distribution, the mean and standard deviation would represent the variability parameters for the particular patient parameter under evaluation, paragraph [0083])

As to claim 16, Seely et al teaches the medical monitoring device as claimed in claim 28 further comprising an alarm indicator that is triggered measurement of histogram data is measured above or below a lower or upper alarm limits, (Alarms can be set so that if a variability histogram is within the normal range, it is displayed in one color (green, for example). If the value of the histogram rises above or falls below the normal range, it is displayed in a different color (red, for example), paragraph [0089]).

As to claim 17, Seely et al teaches the medical monitoring device as claimed in claim 28, wherein the histogram data is binned into histogram bins, the histogram bin size being definable by the user (The data is plotted in frequency bins, where each bin

represents a proportional amount of variation, as measured by the squared difference from the mean, paragraph [0085]; see also Zaleski et al paragraph [0039-0040]).

As to claim 18, Seely et al teaches the medical monitoring device as claimed in claim 28 further comprising display means for displaying real-time signal patterns of the medical measurement data (real-time display, 502, figure 5; note that Zaleski teaches The ongoing results of the analysis (e.g. the trend) may then be transmitted by Application Server 104 back to User Interface 105, such as in the form of a graphical display that is updated in real time; see paragraph [0050]).

As to claim 21, Seely teaches the retrospective analysis aids include at least one of: a cumulative curve cursor for determining a percentage of time that histogram values are below a current cumulative cursor position; range-selection cursors for determining a percentage of time that histogram values are within limits defined by the range-selection cursors; a variability/stability readout that provides information about variability of the measurement data; and a deviation and direction-change readout that shows deviation from a mean histogram value and a direction of measurement data change (The simplest method for computing variability parameters involves the calculation of mean and standard deviation of the frequency distribution of a selected data set. This information can be updated continuously and displayed visually as a graph. Statistical interpretation of the frequency distribution is dependent upon whether the distribution is normal or lognormal. There are standardized means of evaluating whether a distribution is accurately represented by a normal or log-normal curve, which include evaluation of kurtosis and skew. By calculating the kurtosis and skew, the user may be directed

Art Unit: 2624

towards choosing an appropriate distribution. By evaluating the frequency distribution, the mean and standard deviation would represent the variability parameters for the particular patient parameter under evaluation, paragraph [0083])

The limitation of claims 22 and 28 has been addressed above.

As to claims 24 and 26 and 27, Seely teaches the medical monitoring device as claimed in claim 12, wherein the histogram and the cumulative curve are displayed with common axes and scales (figure 5)

As to claim 25, Seely teaches the medical monitoring device as claimed in claim 28, wherein the histogram data includes a series of medical measurement values and the cumulative curve includes a sum of the medical measurement values (paragraph [0085]).

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY BITAR whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali can be reached on 571-272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 2624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nancy Bitar/  
Examiner, Art Unit 2624

/Wes Tucker/  
Primary Examiner, Art Unit 2624